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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/613,220

Filing Date: July 02, 2003 Appellant(s): WADA ET AL.

> Ann C. Peterson For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 22, 2006 appealing from the Office action mailed March 23, 2006.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,007,690	Nelson et al.	12-1999
6.540.895	Spence et al.	4-2003

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (USP#6,007,690) in view of Spence et al (USP#6,540,895).

The claims are broadly drawn to a microfluidic system for detection a component of interest in a sample. Nelson et al teaches a microfluidic devices comprising several alternative embodiments (abstract). In one embodiment, Nelson teaches a microfluidic device that comprise of a first channel and a second channel (figure 18). The first channel has an electrophoretic flowpaths, which examiner interprets as a gel separation region (figure 18, #236) and the region can have on to a plurality of affinity zones, which examiner interprets as the binding regions (column 18, lines 28-32). Nelson et al teaches that the gel is a polyacrylamide (column 11, lines 47). Sample components can be captured by the affinity media in the affinity zones, which satisfies the limitation of step (d) of a component-binding moiety fluidly coupled to the binding region (column 17, lines 63-67). The affinity zones are provided with detectors configured to detect fluorescence or electrochimilluminescence from components of interests (column 17;

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lines 27-31). The binding moieties can comprise of a range of reagents as in lectins, antibodies, biotin binding groups and a variety of proteins (column 17, lines 34-40). The second channel comprise of detection regions (figure 18, #278) and according to the reference, the first channel can also comprise of a detection region for detecting a first analyte (column 10, lines 18-22). The detection regions comprise of detectors and therefore appear to be configured proximal toe the first and second detection regions. Enrichment zones can be positioned in the first and the second channels, which is interpreted as a particle-stacking region (figure 19, #280). According to Nelson, the enrichment channel can employ paramagnetic beads that are coated with affinity medium and can be retained in the channel (column 6, lines 25-29 and column 21, lines 14-23). The beads utilized can also be made of alternative materials as in porous glass and polymeric (column 5, lines 60-63). Nelson discloses several embodiments that include alternative fluid direction systems as a means to transport fluid through the first and second microchannels. One example employs a pumping means for moving a sample through the channel system (column 6, lines 61-62), wherein this pumping means can be interpreted as a pressure based fluid system. The fluid direction system can also be controlled by electrokinetic transport (column 23, lines 10-17). Nelson et al teaches a variety of configurations that can comprise of affinity zones (binding regions). In figure 19, a third channel, downstream of the first two channels comprises electrophoretic flowpaths that can comprise of affinity zones for binding of an analyte.

The device of Nelson et al does not particularly point out a control system linked to the fluid direction system configured to instruct sample transport.

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However, the reference of Spence et al teaches cell sorting utilizing microfluidic systems controlled by a computer or microprocessor that control fluid flow. Different algorithms for sorting in the microfluidic device can be implemented by different computer programs (column 15, lines 6-27).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Nelson et al to include a control system to instruct fluid direction as taught by Spence et al because procedures can be programmed using any suitable software that can perform a variety of functions (column 15, lines 5-27). Further, it is well known in the art to utilize these control systems with microfluidic device systems.

(10) Response to Argument

Appellant's argument that the reference of Nelson nor Spence teaches a second microscale channel configured to contain a particle set that is downstream from a first microscale channel comprising a gel filled component separation region. Appellant additionally argues that neither Nelson nor Spence teaches detection regions associated with both a first and second microscale channel such as recited in claim 1. These arguments have been considered but not found persuasive.

In response, Nelson teaches Figure 16, which is an alternative configuration embodiment to Figure 18 that illustrates an array of affinity zones (Figure 16, #'s 244, 246, 248 and 250) which has lines that run in-between each. The line that connect in-between affinity zone 244 and 246 can be considered to be a second microscale channel. Each of the affinity zones has detectors (i.e. detection regions) and each

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affinity zone has enrichment medium that comprise of oligonucleotides immobilized to beads that will become bound and therefore retained within the detection region to a complementary target (i.e. particle stacking zone). The first microscale channel runs along the main electrophoretec flowpath (Figure 16, #238, i.e. gel separation region) to the first affinity zone and is fluidly coupled to the second channel containing the array of affinity zones (i.e. particle stacking region). Based on the alternative configuration (Figure 16) the second microscale channel is downstream from the first microscale channel, which is required by the instant claim 1.

Appellant argues that the instant invention is used for performing western blot analysis and other intended uses. This argument is noted but not found to be persuasive because the cited reference is also configured to perform western and southern blot analysis among other procedures well known to those skilled in the art.

Appellant argues its fundamental to the invention of Nelson that the enrichment channel be upstream from the main electrophoretic flowpath. This argument is noted but not found persuasive.

In response, in view of the alternative configuration of Nelson (see reasons explained above for Figure 16) the affinity zones (particle stacking regions) comprise of enrichment medium that comprise of oligonucleotides immobilized to beads and will be retained if there is a target complementary probe and detected by the detectors (Figure 16, #'s 243, 245, 247 and 249).

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Appellant argues that the examiner have not identified the first and second microscale channels of figure 19. This argument is noted but not found to be persuasive based on the alternative embodiment of Nelson explained above.

Appellant argues that the examiner have identified its particle stacking region as being the enrichment channel (Figure 19, #280) in the previous Office Actions in which appellant asserts is clearly upstream from the electrophoretic flowpath (Figure 19, #284). These arguments are noted but not found to be persuasive in view of the alternative embodiment of Nelson explained above.

Appellant argues that the reference of Spence does not teach a second microscale channel configured to contain a particle set that is downstream from a first microscale channel comprising a gel filled component separation region. Therefore, Spence cannot supply the limitation missing from Nelson. This argument have been fully considered but not found persuasive.

In response, the reference of Spence was not relied on for those limitations that were already taught in the reference of Nelson. Further, the claims would be anticipated if all of the limitations were taught by Spence. Therefore, it is the examiner's position that the reference of Spence in combination with Nelson is obvious over the instant claimed invention.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

D. A. D.

Deborah A. Davis Patent Examiner Art Unit 1655

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